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PATENT APPLICATION  
Docket No.: 301888,3009-101

UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Guiting Lin, Y. Joseph Mo, Mingqi Lu, Yinglu Guo

Application No.: 10/803,460

Filed Date: 03/18/2004

Confirmation No. 5541

Group: 1614 Examiner: Not Assigned

For: Neuronal Growth Enhancement by Prostaglandin Compositions and Methods

CERTIFICATE OF MAILING	
I Hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
on <u>12/7/04</u>	<u>Lynn F. McMiller</u>
Date	Signature
<u>Lynn F. McMiller</u>	
Typed or printed name of person signing certificate	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(More than 3 months after receipt of the International Search Report, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

- ☒ Copies of the cited references are enclosed.
- ☐ In accordance with 37 C.F.R. § 1.98 (d), copies of cited references (\*list reference not enclosed\*) are not enclosed as these references were entered in earlier application, U.S. Application No. [ ], to which the present application claims priority under 35 U.S.C. 120. The earlier application contains copies of the cited references.
- ☐ If copies of references [\*list references not enclosed\*] would benefit the Examiner of this case, the Examiner is invited to call the undersigned attorney and copies will be forwarded immediately.
- ☐ Listed references [ ] were cited in the enclosed International Search Report in a counterpart foreign application.

Concise Explanation Requirement (non-English references):

- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
  - ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ the enclosed English language abstract.

Application No. 10/803,460

☐ Applicant requests that the following pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_  
U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account No. 50-1935 in the amount of \$[ ]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account No. 50-1935.

Respectfully submitted,

BOWDITCH & DEWEY, LLP

By

  
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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 301888.3009-101		APPLICATION NO. 10/803,460			
SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION 12/6/2004 (Use several sheets if necessary)		APPLICANT NexMed (Holdings), Inc.					
		FILING DATE 3/18/2004		GROUP ART UNIT 1614			
U.S. PATENT DOCUMENTS							
EXAM- -INER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL						
	AM						
	AN						
	AO						
	AP						
	AQ						
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AZ7	Carrier, S., <i>et al.</i> , "Regeneration of Nitric Oxide Synthase-Containing Nerves After Cavernous Nerve Neurotomy in the Rat", <i>J Urol</i> , 153:1722-7 (1995)					
	AR8	Gholami, S.S. <i>et al.</i> , "The Effect of Vascular Endothelial Growth Factor and Adeno-Associated Virus Mediated Brain Derived Neurotrophic Factor on Neurogenic and Vascuogenic Erectile Dysfunction Induced by Hyperlipidemia," <i>J Urol</i> , 169:1577-1581 (2003).					
	AS8	Jung, G.W., <i>et al.</i> , "IGF-I and TGF- $\beta$ 2 Have a Key Role on Regeneration of Nitric Oxide Synthase (NOS)-Containing Nerves After Cavernous Neurotomy in Rats". <i>Int J Impot Res</i> , 11:247-59. (1999)					
EXAMINER			DATE CONSIDERED				

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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AT 8	Jung, G.W., <i>et al.</i> , "The Role of Growth Factor on Regeneration of Nitric Oxide Synthase (NOS)--Containing Nerves After Cavernous Neurotomy in the Rats." <i>Int J Impot Res</i> , 11:227-35 (1999)					
	AU 8	Katoh, H., <i>et al.</i> , "Prostaglandin E Receptor EP3 Subtype Induces Neurite Retraction via Small GTPase Rho*", <i>J Biol Chem</i> , 271(47): 29780-29784 (1996)					
	AV 8	Kawamura, T., <i>et al.</i> , "Prostaglandin E1 Transported into Cells Blocks the Apoptotic Signals Induced by Nerve Growth Factor Deprivation." <i>J Neurochem</i> , 72:1907-14 (1999)					
	AW 8	Kogawa, S., <i>et al.</i> , "Apoptosis and Impaired Axonal Regeneration of Sensory Neurons After Nerve Crush in Diabetic Rats." <i>Neuroreport</i> , 11: 663-667 (2000)					
	AX 8	Lando, M., <i>et al.</i> , "Modulation of Intracellular Cyclic Adenosine Monophosphate Levels and the Differentiation Response of Human Neuroblastoma Cells." <i>Cancer Res</i> , 50:722-727 (1990)					
	AY 8	Mehrabani, M.R., <i>et al.</i> , "Clinical and Experimental Evidence of Prostaglandin E1-induced Angiogenesis in the Myocardium of Patients with Ischemic Heart Disease," <i>Cardiovasc Res</i> , 56:214-224 (2002).					
	AZ 8	Pai, R., <i>et al.</i> , "PGE <sub>2</sub> Stimulates VEGF Expression in Endothelial Cells via ERK2/JNK1 Signaling Pathways," <i>Biochem Biophys Res Commun</i> , 286:923-928 (2001).					
	AR 9	Padma-Nathan, H. <i>et al.</i> , "The Impact on Return of Spontaneous Erections of Short-term Alprostadil Therapy Post Nerve Sparing Prostatectomy," <i>J Urol</i> , 157(4): 363 (abstract 1422).					
EXAMINER				DATE CONSIDERED			

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AS9	Sondell, M., <i>et al.</i> , "Vascular Endothelial Growth Factor is a Neurotrophic Factor which Stimulates Axonal Outgrowth through the Flk-1 Receptor", <i>Eur J Neurosci</i> , 12:4243-4254 (2000)					
	AT 9	Sonobe, M., <i>et al.</i> , "Amelioration of Nerve Na <sup>+</sup> -K <sup>+</sup> -ATPase Activity Independently of Myo-inositol Level by PGE <sub>1</sub> Analogue OP-1206. $\alpha$ -CD in Streptozocin-Induced Diabetic Rats." <i>Diabetes</i> , 40:726-730 (1991)					
	AU 9	Yasuda, H., <i>et al.</i> , "Metabolic Effect of PGE <sub>1</sub> Analogue 01206. $\alpha$ CD on Nerve Na <sup>+</sup> -K <sup>+</sup> -ATPase Activity of Rats with Streptozocin-induced Diabetes is Mediated via cAMP: Possible Role of cAMP in Diabetic Neuropathy." <i>Prostaglandins</i> , 47:367-378 (1994)					
	AV 9	Yasuda, H., <i>et al.</i> , "A Combination of the Aldose Reductase Inhibitor, Statil, and the Prostaglandin E <sub>1</sub> Analogue, OP1206. $\alpha$ CD, Completely Improves Sciatic Motor Nerve Conduction Velocity in Streptozocin-induced Chronically Diabetic Rats." <i>Metabolism</i> , 41(7):778-782 (1992)					
EXAMINER				DATE CONSIDERED			